

510(k) Summary

General InformationK 0 3 2 0 4 7

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Classification	Class II
Trade Name	Tri-Loop™ Microwave Ablation Probe
Submitter	Vivant Medical, Inc. 1916-A Old Middlefield Way Mountain View, CA 94043 (650) 694-2900
Contact	Steven Kim Vice President of Research and Development

Intended Use

The Tri-Loop™ Microwave Ablation Probe is intended for coagulation of soft tissue. Not for use in cardiac procedures.

Predicate Device

Vivant Medical Loop™ Microwave Ablation Probe

K023311

Device Description

The device consists of 3 pre-shaped curved microwave antennas which is contained within 3 delivery cannulas. The cannulas are attached to a handle mechanism that deploys the antennas into the targeted tissue. RF energy can be used to facilitate deployment of the antennas into tissue. The Vivant VivaWave™ Microwave Generator (K011676) is used to deliver the microwave energy to the curved antennas which heats the tissue within and around the antennas.

Materials

All patient contact materials used in the manufacture of the Tri-Loop™ Microwave Ablation Probe are suitable for this use and have been used in numerous previously cleared products.

Summary of Substantial Equivalence

The Tri-Loop™ Microwave Ablation Probe is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Vivant Medical believes the Tri-Loop™ Microwave Ablation Probe is substantially equivalent to existing legally marketed devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Mr. Steven Kim
Vice President of Research and Development
Vivant Medical, Inc.
1916-A Old Middlefield Way
Mountain View, California 94043

Re: K032047

Trade/Device Name: Tri-Loop™ Microwave Ablation Probe

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and
accessories

Regulatory Class: II

Product Code: GEI

Dated: July 1, 2003

Received: July 7, 2003

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

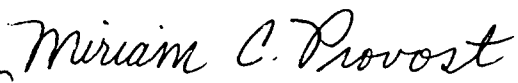
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

This application K032047

Device Name:

Device name TRI-LOOP™ MICROWAVE Ablation Probe

Indications for Use:

The Tri-Loop™ Microwave Ablation Probe is intended for coagulation of soft tissue. Not for use in cardiac procedures.

Bahar Binnur, M.D., C.M.D.
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K032047

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)